REGULATORY GUIDE B3

COMPLYING WITH TITLE B - DENTAL FACILITIES

South Carolina Department of Health
and Environmental Control

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Each dental facility that is registered with the Department is required to comply with Title B, which are the regulations concerning x-ray equipment. This guide is intended to assist the dental facility in complying with Regulation 61-64, X-Rays (Title B).

FACILITY REGISTRATION (See RHB 2.4)

Before installing X-ray equipment, each facility must apply for facility registration approval.
Facility Registration should include:

1) A completed B1 Regulatory Guide.
2) An application fee of $62.50. **(For New Facilities Only)**
3) A shielding plan, and the required shielding plan fee if applicable. (Cephalometric units, and Pan/Ceph combos, and TMJ units)
4) Complete set of Operating Procedures as outlined below.

REQUIREMENTS FOR OPERATING PROCEDURES (See RHB 4.2.4)

All facilities are required to have written operating procedures available to all x-ray operators. It is the responsibility of the registrant to ensure that each operator is familiar with the procedures and competent to operate the x-ray equipment, to include documentation of training, and review of procedures. The procedures must include the following items, as a minimum:

1) **Policies and Procedures for Patient Holding.** The procedures must state whether or not, as a matter of policy, patients will be held at that facility. The availability and use of restraining devices must be addressed. The procedures must indicate the individual projections where mechanical holding devices cannot be used, and a human holder is required. The process to select a human holder must be documented, as well as the procedures that the human holder is to follow. Whenever possible, an adult accompanying the patient should be used for holding. Pregnant females should not be used to hold a patient. Methods for protecting the human holder, such as wearing aprons and gloves, must be included. If a facility is required to hold patients, then procedures to ensure that no one person is used routinely to hold patients must be included. The lead aprons & gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. This testing must be documented. Records of this testing must be kept for two years or until the next Department inspection.

Neither the dentist nor his assistant shall hold patients or films during the exposure, nor shall any individual be regularly used for this service.

2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy must be included. If a facility has policies to remove pregnant workers from performing x-ray exams, then those policies should be stated. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.

3) **Policies and Procedures Regarding the Use of Protective Clothing.** Documentation must be

included on when protective clothing, such as lead aprons and thyroid shields, will be used on patients as a matter of policy. The proper use and placement of protective clothing must be included.

4) **Policies and Procedures for Pregnant Patients.** The procedures must include methods for determining possible patient pregnancy. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate measures are taken.

5) **Policies and Procedures for Personnel Monitoring.** The operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures must tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges must be stated. The location of control badges must be given. The policies for reporting and investigating over-exposures must be stated. A prohibition against intentionally exposing any control or personnel badge must be included. Procedures must also be included instructing workers on how they may obtain the results from the monitoring.

6) **Procedures for Training New Employees.** See below under "Training Plans."

7) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. This may vary widely from facility to facility. At a minimum, two items must be addressed in the quality assurance plan. These are (a) standards for the proper performance of the x-ray system and (b) standards for processing. See below under "Quality Assurance."

REGISTERING EQUIPMENT (See RHB 2.1.1)

All x-ray equipment is required to be registered with the Department. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect his x-ray facility or the x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures. In addition, upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control. The registration stickers shall be placed on the control panel in a clearly visible location.

PERSONNEL MONITORING (See RHB 3.12 and RHB 4.2.16)

Personnel monitoring is required in the following situations:

1) When an employee is likely to receive greater than 10% of their occupational dose limit for one year.
2) When an employee under 18 years of age is likely to receive greater than 5% of their occupational dose limit for one year.
3) When an employee may be required to hold patients more than three times in a quarter. However, neither the dentist nor his assistant shall hold patients or films during the exposure.
4) When an individual enters a high radiation area. (Not likely at a dental facility.)
5) Declared pregnant workers who request an additional badge for monitoring doses underneath lead aprons.

6) When the Department deems that it is necessary.

The Department recommends instituting a personnel monitoring system for a period of at least one year to ensure that all individuals entering a restricted area do not receive a dose in any calendar quarter in excess of 10 percent of the allowable exposure limits. If procedures require an individual's extremities to be in or near the primary beam, then ring badges should also be used. After monitoring for a year, if the doses received are well below 10 percent of the allowable exposure limits, the monitoring may be discontinued. The monitoring should be reinstated if new procedures are added, if the x-ray workload increases, if new employees are given x-ray duties, or after any changes that may affect the doses received. The records from monitoring must be retained indefinitely, even if the service is discontinued.

When a protective lead apron is worn by the operator, and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron. When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual. The Department may give consideration for the use of protective apparel provided that the registrant submits written procedures to ensure that this apparel is worn at all times. Written procedures must be submitted to and approved by the Department prior to the badge under the apron being used as the permanent record.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm.

PRIOR OCCUPATIONAL EXPOSURE (See RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposition.

OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

TRAINING PLANS (See RHB 4.2.3)

Each dental facility is required by RHB 4.2.3.8 to ensure that all x-ray operators are adequately instructed in safe

operating procedures and competent in the safe use of the equipment. Each operator is also required to have instruction in specific areas. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in RHB 4.2.3.8.

Employees who are certified Dental Assistants, registered Dental Hygienist or are certified by the South Carolina Board of Dentistry as a dental x-ray operator are considered to meet the basic training requirements.

In accordance with RHB 4.2.3.7 each certified dental x-ray operator who changes from a facility that only performs bitewing x-rays to a facility where he/she will be performing cephalometric exams would probably need some review training to adequately perform that exam. Facility specific training would also be required. Again, this training would need to be documented.

Records must be maintained of all training provided to each operator. The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

QUALITY ASSURANCE (See RHB 4.2.18)

As stated above, the two items that must be addressed in a quality assurance plan are (1) standards for equipment performance tests (initial and periodic calibrations), (2) standards for processing, and (3) Cassette care if applicable. The following items should be contained in the quality assurance plan, as appropriate:

1) A list of the parameters to be monitored and the frequency of monitoring.
2) A description of the procedures to be used for monitoring each parameter.
3) Procedures to be followed to call problems to the attention of those responsible for correcting them.
4) A list of the records, along with sample forms, that the facility is using. Notations should be made concerning the length of time that each type of record is kept before discarding.
5) Results of acceptance testing of new equipment.

The following items should be checked, at a minimum, for the Department to consider the quality assurance program acceptable. These items are not inclusive of all items that could be addressed in a quality assurance program. Quality assurance programs vary widely from facility to facility, and it is each registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance plan accordingly. Employees of the facility may or may not be the individuals carrying out the quality assurance monitoring listed below. In most facilities, the quality assurance testing will probably be performed by a combination of the facility and an x-ray vendor. A facility that chooses to have a x-ray vendor perform some or all of the quality assurance monitoring must use a vendor that is registered with DHEC to provide those services. A list of registered vendors is available from the Department.

1) Standards for Equipment performance tests. Written standards must be established for the proper performance of each x-ray imaging system under the registrant's control. Routine testing must be carried out every four (4) years, at a minimum, to ensure accordance with the standards. Some x-ray units, because of their high workload, may require testing more frequently. The following items, as appropriate, should be included in the x-ray system standards for dental equipment. Items marked with an asterisk (*) indicate that this item may be tested by the vendor or the facility.

   · Half-value layer (HVL)

- Exposure reproducibility
- mA/mAs linearity
- kVp accuracy
- Timer reproducibility and accuracy
- Visual and audible indication of exposure
- Patient exposure at skin entrance (bitewing and/or periapicals)
- Mechanical support of tubehead
- Integrity of passthrough interlocks
- Integrity of lead aprons, gloves, and other protective clothing *

These items should be checked upon initial installation and after any maintenance or repair that could affect their status: Adherence to the approved shielding plan, if applicable; minimum source to skin distance; x-ray beam size; and proper indication of multiple tubes on units so equipped.

NOTE: Facilities using cephalometric units should refer to Regulatory Guide B2 for assistance in setting standards for performance of the x-ray equipment. Ceph units are considered medical units by the Department and are subject to the requirements for medical units. Therefore Pan/Ceph combo units must be tested in accordance with the guidelines set forth for medical units.

Equipment Performance Tests for Panoramic units must include either HVL or kVp testing.

2) Standards for Processing. The following items should be checked as components of the final diagnostic image obtained. Again, these items are not all inclusive, and should be tailored to meet the individual facility conditions.

a) Processor quality assurance. The quality assurance plan should address the care, maintenance, cleaning, and temperature measurement of the processor.

b) Evaluation of darkroom and film. Darkroom fog conditions should be checked. Darkrooms must be light tight to the dark adapted eye, and should be free from dust and dirt. Daylight film boxes must also be light tight. Record of cassette and screen cleaning for Pan and Cephalometric units.

c) The evaluation of cassettes should be done by assigning each cassette its own number and defining the frequency upon which it is inspected and cleaned, as well as what criteria indicates that the cassette should be replaced

For new facilities, the quality assurance plan will be reviewed by the Department before registration of the x-ray equipment. For existing facilities, the quality assurance plan will be reviewed at the first inspection after the effective date of the regulations. For all facilities, records of quality assurance testing and monitoring will be reviewed on each inspection conducted. Facilities must maintain records for all testing and checks performed.

SHIELDING PLANS (See RHB 4.4)

Before construction, a facility is required to submit a radiation shielding plan for cephalometric and TMJ units to the Department for review and approval to include the applicable shielding plan review fee. The shielding plan must be reviewed by a Class III or a Class IV vendor. See Regulatory Guide B6 for assistance. This only applies to cephalometric units, panoramic/cephalometric combination units, and TMJ units. Intraoral dental units are usually not required to submit shielding plans. The only intraoral dental units that are required to submit a shielding plan are

units installed in a modular layout. Modular dental units do not usually have complete barriers or walls between adjacent x-ray area, and therefore, are required to submit a shielding plan, and may require an area survey. All Dental units must be installed so that the operator must view the patient at all times X-rays are being produced, from a protected area. In addition each control shall provide an audible, or visible signal of exposure.

PASS THROUGHS (See RHB 4.5.11.3)

Each unit that is installed so that it may be shared between rooms shall be installed so that its pass throughs are interlocked. In other words, if the tube is being used in one room, a means must be available to keep the unit from operating if the door in the cabinet to the other room is open.

MANUAL FILM PROCESSING (See RHB 4.2.19.1)

When a facility performs manual film processing, the following items are required to be used by the facility:

1) Processing tanks that are mechanically rigid and corrosion resistant.
2) A dedicated darkroom thermometer to measure developer temperature. Developer temperature must be within 60°F and 80° F (16° C to 27° C).
3) A dedicated darkroom timer to set film processing time.
4) Documentation to show when the film processing chemicals are changed.
5) A darkroom safelight compatible with the type of film being used.
6) A time-temperature developing chart.

SIGHT DEVELOPING OF RADIOGRAPHS IS NOT ACCEPTABLE FOR PROCESSING FILMS.
The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

AUTOMATIC FILM PROCESSING (See RHB 4.2.19.2)

When a facility uses an automatic processor or other closed processing system, the following items are required:

1) Processing chemical temperatures consistent with the type of film(s) being processed.
2) Appropriate film processing chemicals and replenishment rates.
3) A darkroom safelight compatible with the type of film(s) being used.
4) Film immersion times consistent with the developer temperature.

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

OTHER FILM PROCESSING REQUIREMENTS (See RHB 4.2.19)

Film storage boxes in x-ray rooms must be "light-tight" and incorporate adequate shielding to prevent fogging of undeveloped film from stray radiation. Film must be stored in a cool, dry place protected from stray radiation. Film in open packages must be stored in a light tight container. Film should not be stored where it can be exposed to chemical fumes or radiation. Film that is expired or outdated shall not be used, unless it has been properly stored, and passes a sensitometric test for base + fog, and speed.

Film developing solutions should be properly stored; they should never be allowed to freeze. They must be prepared

according to the directions given by the manufacturer, and maintained in strength by replenishment or renewal.

ADMINISTRATIVE REQUIREMENTS (See RHB 4.6.1.1 and RHB 3.15 and RHB 3.16 and RHB 4.2.8.7)

The following items are required to be posted or present at x-ray facilities:

1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign. Only rooms containing cephalometric units are considered to be radiation areas.
2) Technique charts. A technique chart must be posted at each control panel, which states the patient's body part and anatomical size versus technique factors (kVp, mA, and time) to be used. For dental units that have a set kV and mA, the technique chart needs to state the time of exposure that will be used. Some dental units are considered to have a built-in technique chart that selects the mAs when a tooth is selected. In addition the type of film speed being used must be indicated on the technique chart.
3) A sign must be posted in a conspicuous area that notifies patients to inform the technologist if they are pregnant or might be pregnant.
4) The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
5) A "Notice to Employees" must be posted in an area where it can be reviewed by all employees. You may contact the Department for a copy of this form.

MISADMINISTRATIONS (See RHB 1.11)

Misadministration, in a dental office, means the administration of (1) radiation to the wrong patient or (2) performance of a diagnostic or therapeutic procedure other than that ordered by a prescribing physician. Situations that would not constitute misadministration would include, for example, incorrect ordering of an exam, such as ordering a periapical x-ray when a bitewing x-ray was desired. Another example that is not misadministration would be if, after review of films from an exam, a dentist decides that additional views are necessary to adequately image the area of interest. Repeat films performed due to patient motion, processing errors or problems, incorrect patient positioning, or improper radiographic technique selection are not considered misadministrations.

Each registrant must retain records of misadministrations. The record must contain the name of all individuals involved in the misadministration, the patient's social security number or identification number, a brief description of the event, and the action taken, if any, to prevent recurrence. The records of misadministration must be maintained for three years for diagnostic misadministrations.
The action that a registrant must take in response to a misadministration depends on the type of misadministration that occurs. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for Department review, and maintain the records for three years.

OVEREXPOSURES (See RHB 3.9)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives. Immediate, 24 hour, and/or twenty day written notification may be required. See RHB 3.9 concerning radiation levels and the requirements for reporting.

RECORDS

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation, and major components. (RHB 1.10.1)
- Records showing model and serial numbers of all tubes, controls, and beam limiting devices. (RHB 1.10.2.1)
- Tube rating charts and cooling curves. (RHB 1.10.2.2)
- Records of aluminum equivalent filtration of the useful beam for all x-ray units, including any routine variation. (RHB 1.10.2.3)
- Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department. (RHB 1.10.2.5)
- Records of misadministrations. (RHB 1.11.3)
- Records of prior occupational dose for employees. (RHB 3.20)
- Records of personnel monitoring results. (RHB 3.22)
- Records of employee training. (RHB 4.2.3.7)
- Results of periodic testing of x-ray equipment performance standards. (RHB 4.2.18)
- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room. (RHB 4.4.3) (For cephalometric units only.)
- Any other records of routine checks or testing that are required to be carried out.

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities, on a priority system based on the type of facility that is operating. Most dental facilities are on a four year inspection frequency schedule. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Generally, the Department will send a Notice of Inspection letter to a facility about two weeks in advance of the inspection, however sometimes inspections are scheduled by phone. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. The Department does have the right to make unannounced inspections.

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items

such as records. Generally, an inspection requires use of a dental x-ray unit for about thirty minutes per tube. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Having this information readily available at the time of inspection will greatly facilitate the inspection process.

After a facility is inspected, the inspector will conduct an exit interview. The inspector will discuss any items of noncompliance, as well as any other items that the inspector deems relevant. The inspector will leave an inspection report at the conclusion of the inspection. The inspection report will cite any violations of the regulations. The inspector may also make recommendations concerning the x-ray equipment or the facility itself. A facility representative must sign the inspection report acknowledging receipt of the report. All violations are required to be corrected within 60 days of the inspection.

There may be some inspections which may require additional information before they are completed. In these situations, the inspector will send a written report to the facility within approximately two weeks of the inspection. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate the corrective action which will be taken to correct any violations that were found during the inspection, as indicated in the written report. The Department will respond, in writing, to the twenty day notification, and will give a date by which all corrections must be completed. The facility must notify the Department in writing, by this date indicating that all corrections have been made.

All violations are required to be corrected within sixty days of the inspection. The facility has the option of correcting recommendations. The facility must again notify the Department, in writing, that corrections have been made. Each violation and recommendation must be addressed individually. Corrective action must be described for each violation and recommendation. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state that in their response. After the Department has received the sixty day notification and reviewed the corrective action, a completed corrective action letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call or write:

S.C. DHEC
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

Regulatory Guides

B1 - Registration of X-ray Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B – Facilities Utilizing Industrial or Analytical Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B – Mammography
B8 – Bone Densitometers
B9 – Complying with Title B – Veterinary Facilities

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CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports.

_____ Records of previous occupational dose for employees.

_____ Documentation of operator training.

_____ Records from testing x-ray system performance, including calibration and service records, as well as in-house testing.

_____ Records from processing quality assurance program, to include screen cleaning if applicable.

_____ Misadministration records.

_____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as D.A., R.D.H., etc., and the operator's months of formal training to take x-rays. This may be 12 months for a R.D.H. or on-the-job training. List the number of years experience taking x-rays that each operator has.

_____ Operating procedures.

_____ A copy of your shielding plan and/ or area survey if applicable.

_____ A copy of your Facility Registration Approval.

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs, if required.
_____ Posted technique charts.
_____ Posted pregnancy posters.
_____ Posted "Notice to Employees"

Other questions the inspector will ask:

1) What brand, type, size, and speed of film do you use?
2) What brand and type screens do you use? (For cephalometric and TMJ units)
3) Are films ever held during x-ray exams?
4) Are patients ever held during x-ray exams?
5) Who does servicing on the x-ray equipment?